



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2012-0780; FRL-9904-99]

Amendment of a Pesticide Experimental Use Permit; Notice of Receipt of Application; Comment Request

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's receipt of an application from Monsanto Company requesting to amend 524-EUP-104 experimental use permit (EUP) for the plant-incorporated protectants (PIPs) corn event MON 87411 in combination with single and combined traits against lepidoptera and corn rootworm (CRW). The Agency has determined that the amendment request for the permit may be of regional and national significance. Therefore, because of the potential significance, and pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is hereby providing notice of receipt and is seeking comments on this application.

DATES: Comments must be received on or before *[insert date 30 days after date of publication in the Federal Register]*. Submit your comments, identified by docket identification (ID) number and the EUP File Symbol as shown in the body of this document, by one of the following methods:

ADDRESSES: Submit your comments, identified by docket identification (ID) number and the EUP File Symbol as shown in the body of this document, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Robert McNally, Biopesticides and Pollution Prevention Division (BPPD), (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7090; e-mail address:

BPPDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. Although this action may be of particular interest to those persons who conduct or sponsor research on pesticides, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:
- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
 - ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
 - iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
 - iv. Describe any assumptions and provide any technical information and/or data that you used.
 - v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
 - vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticide(s) discussed in this document, compared to the general population.

II. What Action is the Agency Taking?

Under section 5 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136c, EPA can allow manufacturers to field test pesticides under development. Manufacturers are required to obtain an EUP before testing new pesticides or new uses of pesticides if they conduct experimental field tests on 10 acres or more of land or one acre or more of water. Following the review of the application and any comments and data received in response to this solicitation, EPA will decide whether to issue or deny the amended EUP request, and if issued, the conditions under which it is to be conducted. Any issuance of an amended EUP will be announced in the **Federal Register**.

Therefore, pursuant to 40 CFR 172.11(a), the Agency has determined that the following amended EUP application may be of regional and national significance, and therefore is seeking public comment on the following amended EUP application:

524-EUP-104. (EPA–HQ–OPP–2012–0780). On March 1, 2013, EPA approved an application from Monsanto Company, 800 Lindbergh Blvd., St. Louis, MO 63167, for an experimental use permit (EPA Reg. No. 524-EUP-104) for the PIPs corn events MON 87410 and MON 87411. A notice of issuance of the EUP was published in the **Federal Register** on November 21, 2013 (78 FR 69849) (FRL-9403-1) . The corn events MON 87410 and Mon 87411 were approved for experimental use in combination with single and combined traits that produce active ingredients derived from *Bacillus thuringiensis* (*Bt*) and target lepidoptera and corn rootworm (CRW). The EUP allowed planting through February 28, 2015.

In a subsequent application, dated October 3, 2013, Monsanto has proposed to amend this permit (524-EUP-104) to plant MON 87411 in combination with other single- and combined-event PIPs that have been previously registered. The acreage to be planted under the proposed amendment over the 2-year period (2014-2016) are: 13,300 acres of event combinations containing MON 87411, 7,032 acres of other unregistered PIP combinations, 11,057 acres of registered PIPs to be used in comparators, and 14, 653 acres of non-PIP and border plants.

The PIP events comprising the single or combined trait products in this EUP include MON 89034, TC1507, MIR162, MON 88017, DAS-59122-7, and MON 87411. The proposed new corn event, MON 87411, contains a suppression cassette with an inverted repeat sequence (DvSnf7) derived from *Diabrotica virgifera*. The expression of

the DvSnf7 suppression cassette results in the formation of a double stranded RNA (dsRNA) transcript. The researchers postulate that when PIP-produced Dv49 dsRNA is consumed by the pest, it down regulates the targeted pest's *Snf7* gene, resulting in CRW mortality. MON 87411 also produces the Cry3Bb1 protein to protect against CRW larval feeding.

The *Bt* proteins to be used in the single or combination traits in the proposed amended EUP include Cry1A.105, Cry2Ab2, Cry IF, Vip3Aa20, Cry3Bb1, and Cry34Abl/Cry35Abl. The environmental and human health safety of these proteins has been demonstrated, and they are respectively exempted from the requirement of a tolerance (40 CFR 174.502, 174.519, 174.520, 174.501, 174.518, 174.506). A permanent tolerance exemption has been established for nucleic acids that are part of the PIPs proposed for testing, including the dsRNA from MON 87411 (40 CFR 174.507).

The tests will be conducted in the U.S. territory of Puerto Rico and in the states including: Alabama, Arkansas, California, Colorado, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Nebraska, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Washington and Wisconsin.

Proposed protocols for the EUP include: (1) Seed development and increase for future testing including nursery observations of traits in various genetic backgrounds; and (2) product characterization work, including phenotypic and agronomic observations, efficacy, yield benefit evaluations and regulatory data generation.

Authority: 7 U.S.C. 136c.

List of Subjects

Environmental protection, Experimental use permits.

Dated: December 30, 2013.

G. Jeffrey Herndon, Acting

Director, Registration Division, Office of Pesticide Programs.

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